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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,836	12/21/2001	Martina Elisabeth Werner	BTI2 00103401(USP4) US	4194

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EXAMINER	
FORMAN, BETTY J	
ART UNIT	PAPER NUMBER
1634	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	01/05/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 01/05/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com

Office Action Summary	Application No.	Applicant(s)	
	10/035,836	WERNER ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *70-76,78 and 80-86* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *70-76,78 and 80-86* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

FINAL ACTION

Status of the Claims

1. This action is in response to papers filed 26 October 2006 in which claims 70, 76, 78, 81-82, 84 were amended. All of the amendments have been thoroughly reviewed and entered. The previous objections and rejections in the Office Action dated 17 February 2006, not reiterated below, are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection. New grounds for rejection, necessitated by amendment, are discussed.

Claims 70-76 78, 80-86 are under prosecution.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 70-76 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 70-76 are indefinite in Claim 70, lines 7 and 9 for the recitation "said reflective layer" because the recitation lacks proper antecedent basis in the "first reflective layer" of line 5. It is suggested that Claim 70, lines 7 and 9 be amended to insert "first" before "reflective".

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 70-76 are rejected under 35 U.S.C. 102(e) as being anticipated by Zorval et al (U.S. Patent No. 6,965,433, having priority to 60/249,391, filed 16 November 2000).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Regarding Claim 70, Zoval et al disclose a bio-disc comprising a circular substrate adapted to transmit an interrogation beam from an optical drive, a first reflective layer associated with the substrate and adapted to reflect an interrogation beam, a plurality of target zones (window #140) in the reflective layer (#164) wherein the interrogation beam passes through the reflective layer and an active layer (#125) vertically aligned with the reflective layer (#164) and target zone (#140) wherein the active layer comprises immobilized DNA and a second reflective layer covering a portion of the active layer (#148) (Column 6, lines 4-Column 7, line 28 and Fig. 6-10).

Regarding Claim 71, Zoval et al disclose the biodisc further comprising a fluidic circuit associated with the active layer (i.e. channel, Column 4, lines 13-31 and Column 6, lien 4-32).

Regarding Claims 72-73, Zoval et al disclose the biodisc wherein the circuit is formed from an adhesive membrane (Column 4, lines 22-31).

Regarding Claim 74, Zoval et al disclose the biodisc wherein the circuit comprises a flow and return channel (Column 4, lines 22-31).

Regarding Claim 75, Zoval et al disclose the biodisc wherein the channels form a U shape (Column 1, lines 41-43).

Regarding Claim 76, Zoval et al disclose the biodisc further comprising a cap portion (#100/190) in vertical alignment with the second reflective layer, wherein the cap provides an inlet port (#110/210) (Column 4, lines 13-22 and Column 6, lines 65-67).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 78, 80-86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zorval et al (U.S. Patent No. 6,965,433, having priority to 60/249,391, filed 16 November 2000) in view of Curtis et al (U.S. Patent No. 4,390,499, issued 28 June 1983).

Regarding Claim 78, 82 and 84, Zoval et al disclose a bio-disc comprising a circular substrate adapted to transmit an interrogation beam from an optical drive, a first reflective layer associated with the substrate and adapted to reflect an interrogation beam, a plurality of target zones (window #140) in the reflective layer (#164) wherein the interrogation beam passes through the reflective layer and an active layer (#125) vertically aligned with the reflective layer (#164) and target zone (#140) wherein the active layer comprises immobilized DNA and a second reflective layer covering a portion of the active layer (#148) (Column 6, lines 4-Column 7, line 28 and Fig. 6-10). Zoval et al do not teach a break-away wall.

However, Curtis teaches the similar rotating substrate as discussed above and comprising a break-away wall configured to break under "rotational forces" whereby dispensing

of reagents are controlled by programmable rotation (Column 3, lines 59-65). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the break-away wall of Curtis to the rotating substrate of Zoval. One of ordinary skill in the art would have been motivated to do so for the expected benefit of programmable reagent mixing as desired in the art (Curtis, Column 3, lines 59-65).

Regarding Claim 80, Zoval et al disclose the biodisc wherein the circuit is formed from an adhesive membrane (Column 4, lines 22-31).

Regarding Claim 81, Zoval et al disclose the biodisc further comprising a cap portion (#100/190) in vertical alignment with the second reflective layer, wherein the cap provides an inlet port (#110/210) (Column 4, lines 13-22 and Column 6, lines 65-67).

Regarding Claim 83, Zoval et al disclose the biodisc wherein the DNA is covalently anchored (Column 6, lines 4-Column 7, line 28 and Fig. 10-11).

Regarding Claim 85, Zoval et al disclose the biodisc wherein the circuit is formed from an adhesive membrane (Column 4, lines 22-31).

Regarding Claim 86, Zoval et al disclose the biodisc further comprising a cap portion (#100/190) in vertical alignment with the second reflective layer, wherein the cap provides an inlet port (#110/210) (Column 4, lines 13-22 and Column 6, lines 65-67).

8. Claims 78, 80, 81 and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Curtis et al (U.S. Patent No. 4,390,499, issued 28 June 1983) and Wang et al (U.S. Patent No. 5,922,617, issued 13 July 1999).

Regarding Claim 78, Curtis discloses a device comprising a circular substrate (shaft #21) and a plurality of flow channels associated with the substrate, the channels divided by a break-away wall configured to break when the disc rotates at a predetermined speed (Column

5, lines 17-67). Curtis does not teach DNA chemically bound to the active layer. However, active layers having chemically bound DNA were well known in the art at the time the claimed invention was made as taught by Wang et al. Wang et al teach that chemically binding the DNA permits vigorous removal of non-specifically bound materials and enhances detection of higher stringency affinity interactions (Column 9, lines 61-67). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the chemically bound DNA of Wang et al to the bio-disc of Curtis for the expected benefit of detecting high affinity interactions as taught by Wang et al (Column 9, lines 61-67).

Alternatively, Wang et al disclose a similar bio-disc comprising a circular substrate (Fig. 3-5) a reflective layer associated with the substrate (Column 10, lines 38-40), a plurality of target zones disposed in the reflective layer (i.e. on the substrate, Column 3, lines 38-67) and an active layer comprising DNA immobilized through a reactive group (Column 3, lines 56-Column 4, line 9). Wang et al do not teach a break-away retaining wall.

However, Curtis teaches the similar rotating substrate as discussed above and comprising a break-away wall configured to break under "rotational forces" whereby dispensing of reagents are controlled by programmable rotation (Column 3, lines 59-65). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the break-away wall of Curtis to the rotating substrate of Wang. One of ordinary skill in the art would have been motivated to do so for the expected benefit of programmable reagent mixing as desired in the art (Curtis, Column 3, lines 59-65).

Regarding Claim 80, Curtis discloses the channels are formed of a membrane (#17 and Column 5, lines 46-49).

Regarding Claim 81, Curtis discloses the device further comprising a cap #16 associated with an inlet port #15 (Fig. 2).

Regarding Claim 83, Wang disclose the device wherein the DNA is covalently bound to the active layer (Column 3, lines 56-Column 4, line 9).

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 77-78 are rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 6-8, 10-11 and 137-145 of previously copending Application No. 10/194,396, which is now issued as Claims 1-18 of U.S. Patent No. 7,141,416 . Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to bio-disc comprising a circular substrate, a reflective layer (metal layer), an active layer and target zones. The claim sets merely differ in that the '396 claims are further drawn to a waste reservoir. However, the instant claim language "comprising" encompasses the additional element of the '396 claims. Therefore, the instantly claimed bio-disc is an obvious in view of the bio-disc of the '396 claim set.

Response to Comments

11. Applicant has not traversed the above rejection. The rejection is maintained and made Final.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions

daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
December 27, 2006